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SEP 29 2006

Docket No.: 1059-007IN THE UNITED STATES PATENT AND TRADEMARK
PATENT OPERATION

In re Application of:)
)
 Barry Libin) Group Art Unit: 1614
)
 Serial No.: 09/224,781) Examiner: Krass, Frederick
)
 Filed: January 4, 1999)
)
 For: METHOD OF PREVENTING AND TREATING MUCOSAL AND
 DERMAL CONDITIONS

New York, NY 10036
September 29, 2006Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450APPEAL BRIEF

Sir:

This is an substitute appeal brief which is being filed in response to Notice of a Non-Compliant Brief that was mailed from the final decision of the Examiner which rejected all claims.

(i) *Real party in interest.* The real party in interest is BML Pharmaceuticals Inc.

(ii) *Related appeals and interferences.* There are no known related appeals or interferences.

(iii) *Status of claims.* All claims have been rejected for anticipation and obviousness.

(iv) *Status of amendments.* There are no unentered amendments.

(v) *Summary of claimed subject matter.* The application contains 8 claims which are directed to method of treating fungal disease sites using a composition comprising triclosan alone or in combination with a cationic agent.

Claims 23 and 26 are the independent claims:

Claim 23 is directed to a method of treating fungal infections which is based on contacting fungal disease sites with an amount of triclosan which is effective to alleviate the symptoms of a fungal infection.

Claim 26 is directed to a method of treating fungal infections which comprises contacting disease sites with a composition of triclosan and an cationic antimicrobial agent in an amount which is effective to treat a fungal infections.

(vi) *Grounds of rejection to be reviewed on appeal.* The following rejections are to be reviewed on appeal:

1. Should claims 23-25 be rejected under 35 U.S.C. §102(b) as anticipated by EP 0 670 711B1?

2. Should claims 23-25 be rejected under 35 U.S.C. §102(b) as anticipated by GB 2 160 099A?

3. Should Claims 23-30 be rejected under 35 U.S.C. §103(a) over Libin in view of EP 0 670 711B1?

(vii) Argument.

Rejection No. 1

Claims 23-25 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 670 711B1 ('711 patent).

This ground of rejection is in error because the cited reference requires the presence of additional active materials that are excluded by the terms of claims 23-25. The amended claims, which include the recitation "consisting essentially of", exclude the use of the polypeptide antibiotic nisin which is an essential component of the '711 compositions. For this reason, the amended claims are not anticipated by the '711 patent.

All of the disclosed compositions for use according to the method of the '711 patent employ nisin as well as other components which can include triclosan. Claims 23-25 include the recitation "consisting essentially of" and therefore exclude the presence of nisin.

It is well known and accepted that the transitional phrase "consisting essentially of" limits the materials that could be considered as a part of the claimed composition to those materials that do not have any material effect on the claimed composition. Nisin is a polypeptide antibiotic according to the '711 patent and therefore would have a profound and material effect on the properties of the compositions of the '711 patent. The phrase "consisting essentially of", when used with triclosan, excludes other active materials because the specification and claims clearly contemplate the use of triclosan alone as the sole antifungal agent. Pages 9-11 of the original specification disclosed a number of compositions with

triclosan as the sole active ingredient. Under the rationale of *In re Janakirama-Rao*, 137 USPQ 893, 895-896 (CCPA 1963, claims 23-25 should not be read as including nisin because this interpretation of the claims would be contrary to the applicants specification.

Claim 24

Claim 24 is not anticipated by the '711 patent because the '711 patent does not disclose the use of a solubilizer.

Claim 25

Claim 25 is not anticipated by the '711 patent because that patent does not disclose a semi-solid composition.

For these reasons, it is requested that this ground of rejection be reversed.

Rejection No. 2

Claims 23-25 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by GB 2 160 099A. ('099 patent).

This ground of rejection is also error because the cited reference requires the presence of additional active materials that are excluded by the terms of claims 23-25. The claims, which include the recitation "consisting essentially of", exclude the use of urea which the '099 patent describes as a necessary "horny substance softening agent." For this reason, the amended claims are not anticipated by the '711 patent.

All of the disclosed compositions for use

according to the method of the '099 patent employ urea as well as triclosan. Claims 23-25 include the recitation "consisting essentially of" and therefore exclude the presence of urea.

As noted above, the Transitional phrase "consisting essentially of" limits the materials that could be considered as a part of the claimed composition to those materials that do not have any material effect on the claimed composition. Urea is present in all of the compositions of the '099 patent for the purpose of softening horny skin substances and therefore the presence of this material has a physiological effect on the properties of the compositions of the '099 patent. The phrase "consisting essentially of" when used with triclosan excludes urea because the specification and claims of the present application clearly contemplates the use of triclosan alone as the sole antifungal agent. Pages 9-11 of the original specification disclosed a number of compositions with triclosan as the sole active ingredient. As noted above, under the rationale of *In re Janakirama-Rao*, 137 USPQ 893, 895-896 (CCPA 1963, the presence of urea should not be read into the text of claims 23-25 based on the applicants specification.

Claim 24

Claim 24 is not anticipated by the '711 patent because the '711 patent does not disclose the use of a solubilizer.

Claim 25

Claim 25 is not anticipated by the '711 patent because that patent does not disclose a semi-solid composition.

For these reasons, it is requested that this ground of rejection be reversed.

Rejection No. 3

Claims 23-30 were separately rejected under 35 U.S.C. §103(a) as being unpatentable over Libin in view of EP 0 670 711B1 ('711 patent).

This ground of rejection is in error because the primary reference does not teach the use of the disclosed compositions for antifungal purposes and the '711 patent only mentions the antifungal utility of triclosan in combination with the antibiotic nisin. Claims 23-25 are specific to the use of triclosan alone as they recite that the method consists essentially of the use of triclosan. Claim 26 recites the use of triclosan and a cationic agent for treating fungal infections. Claim 28 is specific to the use of a composition which consists essentially of triclosan and cetyl pyridinium chloride for contacting fungal disease sites and claims 29 and 30 are specific to the use of compositions of triclosan and a cationic agent which have a solubilizer or are in semi-solid form. The Libin patent is concerned with the treatment of periodontitis with a mouth wash containing triclosan and a cationic agent such as cetyl pyridinium chloride. The rejected claims do not claim the compositions disclosed by Libin per se but rather the use of those compositions for treating fungal infections. Libin does not explicitly mention or suggest the treatment of a fungal disease.

The '711 patent always uses nisin in combination with the triclosan component and nisin is not a cationic agent. In addition, the '711 patent does not show the use of triclosan alone or in combination with a cationic agent for treating a fungal condition. The

text of the '711 patent mentions that nisin is always present and that it may be used either with cetyl pyridinium chloride or triclosan. The nisin component is always present and the transitional phrase "consisting essentially of" is properly used to exclude this component because based on the text of the '711 patent one would not be directed to exclude nisin as it is a key component having a material effect on the properties of the composition.

As noted above, the text of claim 26 recites that the claimed method "consists essentially of" the use of triclosan and a cationic agent. This is not made obvious by the combined teachings of the cited references.

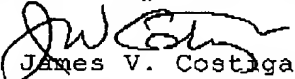
There is no teaching or direction in either of the cited references which tells the skilled artisan to delete the nisin component of the '711 patent or to use the combination of a cationic agent and triclosan to treat a fungal infection.

As noted above, the transitional phrase "consisting essentially of" limits the materials that could be considered as a part of the claimed composition to those materials that do not have any material effect on the claimed method. Nisin is present in all of the compositions of the '711 patent for the purpose of exerting a therapeutic effects and therefore the presence of this material has a physiological effect on the properties of the compositions of the '711 patent. The phrase "consisting essentially of" when used with triclosan and a cationic agent excludes nisin because the specification and claims of the present application clearly contemplates the use of triclosan and a cationic agent as the active antifungal agents. Pages 7-8 of the original specification disclosed a number of compositions with triclosan and a cationic agent as the sole active

ingredient. AS noted above, under the rationale of *In re Janakirama-Rao*, 137 USPQ 893, 895-896 (CCPA 1963, the presence of urea should not be read into the text of claims 26-30 based on the applicants specification.

For these reasons, it is requested that this ground of rejection be reversed.

Respectfully submitted,


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(viii) *Claims Appendix.*

1-22 (canceled)

23. A method of treating fungal infections, said method comprising contacting fungal disease sites with an amount of a composition which consists essentially of triclosan which is effective to alleviate the symptoms of said fungal infection.

24. A method of treating fungal infections as defined in claim 23 wherein the triclosan is combined in a liquid formulation with a solubliizer.

25. A method of treating fungal infections as defined in claim 23 wherein the triclosan is in a semi-solid formulation.

26. A method of treating fungal infections said method comprising contacting fungal disease sites with an amount of a composition which comprises triclosan and a cationic antimicrobial agent in amounts which are effective to alleviate the symptoms of said fungal infections.

27. A method of treating fungal infections as defined in claim 26 wherein the cationic antimicrobial agent is selected from the group consisting of chlorhexidine, cetylpyridium chloride, benzalkonium chloride, benzethonium chloride, methylbenzethonium chloride and domiphen bromide.

28. A method of treating fungal infections as defined in claim 26 wherein the cationic antimicrobial agent is cetylpyridinium chloride.

29. A method of treating fungal infections as defined

in claim 26 wherein the triclosan and the cationic antimicrobial agent are combined in a liquid formulation with a solubilizer.

30. A method of treating fungal infections as defined in claim 26 wherein the triclosan and the cationic antimicrobial agent are combined in a semi-solid formulation.

31-32. (canceled)

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(ix) *Evidence Appendix*

No evidence has been submitted in connection with this application.

(x) *Related Proceedings Appendix.*

There are no related proceedings.

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